

comprising administering to the individual a proportion shifting effective amount of forskohlin.

a² cancelled
6j 27. The method of claim *5* 26, wherein the forskohlin is administered in a daily dose of about 10 to about 60 mg.

7i 28. The method of claim *6* 27, wherein the daily dose is divided into a plurality of individual doses.

8j 29. The method of claim *5* 26, wherein the forskohlin is administered in an individual dose of about 10 to about 20 mg. --

REMARKS

Applicants have carefully reviewed the Office Action dated December 12, 1997, and submit the amendments above and the remarks to follow as a full and complete response thereto.

Claims 1-25 are currently pending. In this Response, applicants cancel claims 5-25, without prejudice or disclaimer, amend claim 1, and add new claims 26-29. Support for the new claims can be found on page 5, lines 9-11. Applicants submit that new claims 26-29 are properly examinable with elected Group I, drawn to a method for promoting lean body mass. Claims 1-4 and 26-29 are presented for reconsideration.

Claims 1-4, 10-13 and 19-24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Wachtel et al. The Examiner notes that Wachtel et al teach the administration of forskohlin to mice in an amount up to 25 mg/kg (the Examiner refers to Table 1, page 431, column 2). The Examiner seems to be taking the position that in view

of the use disclosed in Wachtel et al, one of ordinary skill in the art would be motivated to use forskohlin in the method as set forth in claims 1-4.

This rejection will be discussed regarding claims 1-4, as amended, and new claims 26-29.

Amended claim 1 is directed to a method of promoting lean body mass in a human individual in need thereof. Claim 26 also contains similar limitations. These amendments clearly distinguish claims 1-4 and 26-29 from Wachtel et al in two ways. First, Wachtel et al show the administration of forskohlin to mice, not humans. Second, by adding "in need thereof" applicants mean that the claims are directed to the treatment of individuals for the purpose of promoting lean body mass or shifting the proportion of lean body mass and adipose tissue in favor of lean body mass. In other words, the claims are intended to cover the use of forskohlin as part of a dietary regimen, and the use claimed in the present invention is not intended to be as an anti-depressant.

Wachtel et al merely disclose that forskohlin was administered to study anti-depressant activity of forskohlin. Thus, there is absolutely no disclosure in Wachtel et al of the administration of forskohlin as a dietary supplement for the purpose of promoting lean body mass in a human individual in need thereof, or for shifting the proportion of lean body mass and adipose tissue in favor of lean body mass. Therefore, Wachtel et al does not render claims 1-4, as amended, and new claims 26-29 obvious. In order to be a valid reference under 35 U.S.C. § 103, the prior art must suggest the desirability of the claimed invention. In order to base a rejection under 35 U.S.C. § 103 on a single reference, the reference must teach one of ordinary skill, having the reference before him, to make the proposed modification. *In re Linter*, 173 USPQ 560 (CCPA 1972). Since Wachtel does

not even remotely suggest administering forskohlin in a human individual for the dietary purposes of promoting lean body mass or shifting the proportion of mass in favor of lean body mass, claims 1-4, as amended, and new claims 26-29, are not obvious in view of Wachtel et al.

In view of the amendments and remarks above, applicants submit that this application is in condition for allowance and request reconsideration and favorable action thereon.

If for any reason, the Examiner feels the application is not now in condition for allowance, it is respectfully requested that the Examiner contact, by telephone, applicants' undersigned attorney at the indicated telephone number to arrange for an interview to expedite the disposition of this application.

In the event this paper is not timely filed, applicants hereby petition for an appropriate extension of time. The fee for this extension may be charged to our Deposit Account No. 14-1060, along with any other fees which may be required with respect to this application.

Respectfully submitted,
NIKAIDO, MARMELESTEIN, MURRAY & ORAM LLP



Richard J. Berman
Attorney for Applicants
Registration No. 39,107

Atty. Docket No. P8064-6032
Metropolitan Square
655 Fifteenth Street, N.W.
Suite 330 - G Street Lobby
Washington, D.C. 20005-5701
(202) 638-5000
RJB:vrj